

**Premarket Approval (PMA) Package for
Dockets Management Branch**

**PMA Number P030052
Docket # 2005M-0130**

**Vysis, Inc.
UroVysion™ Bladder Cancer Kit**

Includes:

**Approval Order
Summary of Safety and Effectiveness Data (SSED)
Labeling**

2005M-0130

AAV 1